AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

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VIA ELECTRONIC MAIL
regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-6082-NC, Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Dear Ms. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) on Reducing Administrative Burden. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 85 hospitals and more than 300 other health care facilities in 16 states.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. With such diverse facilities, populations served and geographical locations, we strive to provide an objective and sound policy voice.

We commend CMS for its efforts to reduce regulatory burden and welcome the opportunity to continue collaborating with the Agency. As recognized by a report from the American Hospital Association, hospitals spend nearly $39 billion on administrative activities each year.[1] These are resources that could be spend on patient care. Our comments are composed of recommendations from health care experts across industries including finance, case management, information technology, hospitalists and post-acute care providers. Specifically, we offer comments to CMS on the following issue areas:

- De Minimis Rotations of Hospital Residents
- Stark Modernization
- Guiding Patients to the Best Provider
- Immediate Jeopardy
- Changes to 42 CFR Part 2
- Emergency Medical Treatment and Labor Act
- Readmissions in Quality Programs
- Changes to the Inpatient Only List
- Prior-Authorization Process
- Medicare as Secondary Payer

[1] American Hospital Association, Regulatory Overload (2018)

- Overlapping Claims Rejections
- Medicare Notices
- Three-Day Skilled Nursing Facility Rule
- Home Health Services
- Hospice Emergency Preparedness Testing
- The Protecting Access to Medicare Act of 2014
- Clinical Laboratory Improvement
- The Implementation of Medicare Regulations

De Minimis Rotations of Hospital Residents

To date, many hospitals are limited in their ability to start a Graduate Medical Education (GME) program because of an unintended Per-Resident Amount (PRA) cap that is triggered when a hospital hosts residents for training rotations. As part of their training, residents participating in GME programs rotate to non-teaching hospitals to gain experience in various specialties and in serving different populations. However, due to informal interpretations by CMS, non-teaching hospitals are having their PRA cap triggered when hosting residents, no matter how short the rotation. This impedes the ability of hospitals to start a residency program of their own in the future and penalizes hospitals that want to host residents.

AHPA recommends that CMS specify, through regulatory guidance, that neither a hospital's PRA nor its cap-building window be triggered by the presence of a small number of residents performing brief rotations at a hospital. We also urge the Agency to lift the PRA cap for those hospitals who had it inadvertently triggered because of hosting residents. Many residency programs are based in settings in which the clinical experience available to the residents is limited. To provide broad clinical experience, residency programs ideally have their residents do rotations at other institutions. Residency programs are an important tool in expanding access and combating the growing physician shortage. This is particularly true in rural communities—residents who train in rural settings are far more likely to continue to practice in those communities upon completion.[2] Due to CMS' PRA restriction, rural communities can miss out on opportunities for residents to experience practicing in rural settings at a time when these hospitals are in desperate need of trained physicians. Residents are also, essentially, precluded from an educational exposure that may be necessary to ensure a comprehensive clinical experience.

AHPA is confident that CMS has the statutory authority to conclude that de minimis rotations do not trigger a cap. In the *Balanced Budget Act of 1997* (BBA), Congress capped for the first time the total number of residency positions that Medicare would support for new programs. However, Congress did not

[2] Kaufman, A. Alfero, C., A State-Based Strategy for Expanding Primary Care.

define what constitutes a new residency program or dictate a methodology for determining cap adjustments for new programs. These decisions were left for CMS to address through rulemaking. The BBA states:

> "The Secretary shall, consistent with the principles [in the same subsection governing resident caps], prescribe rules for the application of [resident caps] in the case of medical residency training programs established on or after January 1, 1995."[3]

Throughout the years, CMS has exercised the authority granted by the BBA to interpret the cap rules for new GME programs. For example, in 2012, CMS extended the cap-building period for new programs from three to five years. This change was not the result of legislative action. In extending the cap-building period, CMS stated that the Agency was seeking to address "concerns about teaching hospitals having insufficient time to 'grow' their new residency training programs and to establish an appropriately reflective permanent FTE resident cap."[4]

Stark Modernization

Congress enacted the Stark Law to prohibit physicians from referring Designated Health Services (DHS) payable by Medicare or Medicaid to any entity with which the physician had a financial relationship. While the law was created with the intention of curbing overutilization of resources inherent in a Fee-For-Service (FFS) environment, the regulation has become increasingly outdated and costly to providers. As we shift to a value-based system, the Stark Law continues to penalize providers and impede hospitals and physicians from coordinating care across the continuum.

AHPA recommends that CMS create a Stark regulatory exception for clinical integration arrangements. Many of the Stark Law rules are incompatible with value-based payment models that both Congress and CMS are promoting. This is highlighted by the fact that regulatory waivers have been issued for innovative payment and service delivery models such as the Medicare Shared Savings Program (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI) and the Accountable Care Organization (ACO) Program. The extent of these waivers inherently shows the conflict between payment reform and the current regulatory model.

To continue to make the shift to value-based care, hospitals must be able to financially align themselves with shared incentives, shared resources and seamless technology. For example, in rural settings that have

[3] 42 U.S.C. § 1395ww(h)(4)(H)(i).
[4] 77 Federal Register. 53258, 53416 et seq. (August 31, 2012). Retrieved at: https://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/FR-2012-08-31.pdf.

limited providers, a hospitalist may have a limited pool of Post-Acute Care (PAC) providers as a referral base. Having shared information and incentives will better allow these providers to coordinate care. However, the Stark Law impedes such alignment and innovation. The Stark Law also places unreasonable constraints on how hospitals may finance the infrastructure needed to support a physician in diagnosing and ordering treatments for a patient. For example, without the ability to finance Electronic Health Records (EHRs), a patient's treatment and diagnosis may be hampered. Due to current laws, hospitals cannot partner with physicians to finance these needed tools.

Moreover, under the Stark Law and the Medicare Conditions of Participation (CoPs), hospitals cannot provide any incentive to physician partners to be more efficient in the ordering of services. Even hospitals that operate in a consolidated, employment-only model are severely constrained in their ability to coordinate and incentivize their physicians to practice high quality, evidence-based medical care. We believe that this is contrary to CMS' goal of transitioning to a value-based system.

AHPA recommends that CMS, through rulemaking, interpret the Stark Law in a way that enables providers to have a high degree of confidence that their claims comply with the statute. As a strict liability statute, the Stark Law's breadth, complexity and inscrutability has created a minefield for the health care industry. Whether the complete scope of needed reforms can be accomplished without legislative action is doubtful, but we think CMS has the authority to significantly improve the current situation. It can implement the Stark Law, through rulemaking and published interpretations, in a way that is consistent with the goals of health care reform. CMS should interpret the statute so that well-intentioned and diligent health care providers are not penalized with overpayment and liability.

Specifically, we request that CMS clarify the definitions of volume and value standards, fair market value and commercial reasonableness. The volume and value standards constrain any arrangements that seek to compensate physicians for cost-efficient care and use of resources in the inpatient and outpatient settings, including such simple actions as compliance with an evidence-based clinical protocol. By definition, a reduction in costs for patient care reimbursed on a prospective fixed basis (whether Diagnosis Related Group or Ambulatory Payment Classification) results in increased profits (or reduced loss) for that episode of care. Thus, any sharing of those savings with physicians arguably results in compensation that varies with or considers the "value" of the referral. Since physicians control the great majority of patient care inputs, any meaningful attempt to constrain costs must incentivize them.

Importantly, the very vagueness and ambiguity in the critical terms "fair market value," "take into account volume or value," and "commercial reasonableness," combined with the enormous potential for

disallowed claims and False Claims Act damages and penalties, make prudent providers extremely wary of adopting innovative compensation methodologies. Given the strict-liability structure of Stark, providers cannot rely on expert counsels' advice and have no assurance that CMS, the Office of the Inspector General (OIG), the Department of Justice (DOJ), or a relator will not challenge any innovative compensation methodology. Moreover, providers have the burden of proof that they comply with the conditions in the exceptions. Simply put, given the ambiguity of critical terms, the exceptions are not reliable protection, thereby chilling adoption of innovative arrangements.

AHPA also recommends that CMS extend regulatory waivers to commercial plans. The Center for Medicare and Medicaid Innovation (CMMI) and the OIG have the authority to expand both the Medicare Shared Shavings Program (MSSP) and the CMMI program waivers to corresponding coordinated care arrangements with commercial plans that are aligned with the aims of the MSSP and CMMI payment models. Now that ACOs engage in both Medicare and commercial markets, the government should allow waivers to be applied to commercial relationships as well. This would incentivize greater physician participation in ACOs and other CMMI programs, which would be consistent with the principles applicable to these Medicare programs.

Guiding Patients to the Best Provider

The Medicare statute states that any individual who is entitled to benefits under Medicare Part A or Part B may obtain health services from any institution, agency or person that is qualified to provide services under Medicare. The Medicare CoPs require providers to inform patients of their right to choose any PAC provider. They also prohibit providers from limiting the providers that are available to a patient. Hospitals must provide the patient with a list from which the patient may openly choose a PAC provider.

AHPA believes that there must be a reasonable constraint upon patient choice when that choice can result in a beneficiary receiving care from a low-quality provider, such as one who has higher rates of readmission, infection or referral back to the physician for the treatment of the patient. **We recommend that CMS make a policy determination of what balance the Agency wishes to achieve between open choice and quality of care.** If there is a desire to institute a program that will lead to efficiency and improved quality of care, then there also must be increased guidance to beneficiaries on their choice of PAC providers.

As hospitals develop preferred-provider PAC networks, CMS should provide further guidance on patient-steering regulations so that hospitals can direct patients to high-quality performers. For

example, hospitals should be allowed to share a list of their preferred-provider network as opposed to an entire list of PAC providers, some which may have very low quality ratings. A preferred provider list would consist of facilities that are high performers on CMS' quality metrics, such as star ratings, readmission rates and unscheduled returns to the ED. In rural areas or other areas with limited PAC providers, the entire provider list can be shared.

Immediate Jeopardy

To participate in the Medicare program, acute, critical access and psychiatric hospitals are required to be in "substantial" compliance with each CoP. There are two different types of citations that CMS can issue when a hospital is in non-compliance with a CoP: A Standard-Level Deficiency and a Condition-Level Deficiency. Within the Condition-Level Deficiency, there is a more severe citation available called Immediate Jeopardy (IJ). Providers that receive an IJ are placed on a 23-day termination track from the Medicare and Medicaid programs if they fail to correct the deficiencies. AHPA believes that IJ guidelines need to be revised because the definition of IJ is too subjective, which leads to inconsistency among surveyors seeking to implement the guidelines. An IJ arises in a situation in which "the provider's non-compliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment or death to a resident." We believe that the ambiguity behind what is considered "serious harm" or "potential harm" can often lead surveyors to use the IJ citation more often than appropriate.

Although the Medicare State Operations Manual specifies 10 different triggers to alert surveyors of a potential IJ, these triggers are very broad and can be subject to various interpretations. For example, if a nurse engages in a dispute with a patient, the patient may claim psychological harm, causing the hospital to receive an IJ citation. What is considered psychological harm is subject to the surveyor's interpretation and because there are no tools to capture the level of psychological harm, the surveyor may likely issue an IJ citation to the facility.

In health care settings, there exists a continuum of harm from mild to severe. As health care providers, we must work to effectively improve the delivery of care while reducing harm. However, it is important to match process-improvement resources to the level of harm identified in each case. **We believe that the current IJ process does not capture this continuum of harm. Therefore, AHPA recommends that CMS expand the types of findings available to state survey teams.** This could be done by developing a condition-level scale with different categories depending on the severity and scope of harm identified. The scale would capture the following issues:

- The nature, incidence, degree, manner and duration of the deficiencies or non-compliance.
- The presence of repeat deficiencies and the provider's compliance history in general.
- Whether the deficiencies found are isolated or widespread.
- Whether the deficiencies are directly related to a failure to provide quality patient care.
- Whether the deficiencies indicate a system wide failure of providing quality care.
- The timing of the deficiencies and whether a correction plan has already been implemented.

Adopting this broader scale would allow surveyors to more accurately capture the different levels of harm that can be found in health care. Consequently, IJ citations would be used more appropriately to reflect their original intent. An IJ citation would only be used in cases when an identified process must be immediately stopped and redesigned to ensure that no further serious or potential harm occurs. To receive an IJ, there would have to be a clear indication that any delay to change the care environment of the patient will result in serious harm or death.

AHPA believes that CMS has the statutory authority to revise the current IJ guidelines. Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary of the Department of Health and Human Services (HHS) finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary can establish and change regulatory requirements that a hospital must meet to participate in Medicare. **Therefore, AHPA urges the Agency to explore revising the current IJ regulations so that they more appropriately reflect their original intent. This may be done in collaboration with health providers and surveyors.**

<u>Creation of an Ombudsman Office</u>

AHPA urges the Agency to consider creating an Ombudsman office to address issues related to IJ citations. Despite the subjective nature of IJ, providers have very limited options to contest the findings of state surveyor teams. A provider can only appeal certain actions that are considered to constitute an "Initial Determination" by CMS. Unfortunately, the deficiencies leading to an IJ citation are not considered by CMS an "Initial Determination" and therefore cannot be challenged until the provider actually receives a termination notice from the Agency. According to Section 498.3(d) of the Act, "Initial Determinations" include whether a prospective provider qualifies as a provider, whether a prospective

department of a provider qualifies as provider-based and whether a provider should be terminated because it no longer meets the CoPs.

AHPA believes that hospitals should be given the opportunity to contest the deficiencies related to an IJ as soon as they are identified. There should be a process for hospitals to communicate directly with the Agency about the issues for which the hospital is being cited. Waiting for the termination notice to be issued to address the IJ findings is, in our opinion, an unfair practice to health care providers. Addressing a hospital's deficiencies as soon as they are identified is particularly important given that CMS publicizes all IJ citations. We recommend that CMS consider creating an Ombudsman program that will allow providers to address issues related to an IJ citation. This could include issues related to a surveyor's interpretation of Medicare policies and regulations or complaints regarding the inaccurate use of an IJ by a surveyor. We believe that having a process in place for hospitals, surveyors and CMS to discuss the findings related to an IJ would allow for due process. It would also make state surveyors more accountable for their use of IJ citations.

Changes to 42 CFR Part 2

The 42 CFR Part 2 regulation currently protects the confidentiality of a patient's substance use records. The regulation seeks to encourage people to seek treatment without fear of any potential consequences. To protect the patient against any stigma, a patient's substance use records are separated from the medical records.

AHPA recommends that CMS revise the 42 CFR Part 2 regulation so that it is better aligned with the Health Insurance Portability and Accountability Act (HIPAA). A significant obstacle to sharing information among providers is the lack of alignment between 42 CFR Part 2 and HIPAA. Although changes have been made, 42 CFR Part 2 remains a burden because the privacy protections travel with the information. This differs from HIPAA and other confidentiality laws that recognize information recipients may not be subject to the same privacy restrictions as the entity that disclosed the information. This additional restriction leaves providers with limited information about a patient's clinical history and inhibits their ability to make the best possible decision about a patient's care. Lack of access to a patient's substance use records can result in a physician inadvertently prescribing opioids to a patient with a prior history of addiction. This puts the patient at greater risk of having an adverse outcome. Physicians need access to a patient's complete medical history, including information related to any substance use disorder, to ensure their patients' safety. Obtaining multiple consents from a patient is also challenging and creates administrative barriers to providing timely, whole-person treatment.

The Emergency Medical Treatment and Labor Act

The Emergency Medical Treatment and Labor Act (EMTALA) requires that any person presenting at a hospital's ED be screened for an emergent condition and subsequently stabilized and treated if needed, preserving access to care regardless of financial status. AHPA believes EMTALA to be an important safeguard that could benefit from continued modernization as the health care community works to lower the cost of care.

We affirm CMS for its development of new innovations to reduce unnecessary ED utilization, such as the Emergency Triage, Treatment, and Transport (ET3) model. This model allows ambulance care teams to triage and direct patients to a hospital ED or urgent care clinic, which CMS hopes will help to keep costs more affordable for patients. **AHPA believes that ED physicians, as well as Physician Assistants, should similarly be able to direct patients to the most appropriate care setting based on their presenting clinical condition.**

All patients presenting at an ED are not necessarily experiencing an emergency. At times, clinical judgement is needed to determine whether a patient can safely be cared for in an urgent or primary care office. Patients presenting with cold symptoms, for example, could be triaged and connected with a co-located urgent care clinic, saving them the expense of an ED visit. To preserve patient access protections, CMS could institute guardrails to ensure that all patients still receive necessary care. In 2013, CMS convened a Technical Advisory Group to advise the Secretary on modernizing EMTALA. **AHPA recommends that CMS convene another Technical Advisory Group to review and update any outdated EMTALA regulations that inadvertently inhibit hospital innovation and prevent clinicians from connecting non-emergent patients with the most appropriate health care setting.**

Readmissions in Quality Programs

Under the Medicare Hospital Readmissions Reduction Program (HRRP), hospitals are penalized for all readmissions, even those that are not preventable or associated with the care delivered at the hospital. Additionally, HRRP does not account for social risk factors that may influence patient outcomes. This policy places hospitals that treat a disproportionate share of vulnerable populations at a significant financial disadvantage.

AHPA believes that CMS can simplify readmission policies to avoid unfairly penalizing providers for circumstances outside of their control. **Within the quality reporting programs, we believe that CMS should only account for *unplanned* readmissions that are related to a previous admission or**

diagnosis. For example**,** hospital readmissions should not be accounted for if they are planned due to treatment staging or recurring blood transfusions for other treatments. Similarly, hospitals should not be penalized for readmissions that are unrelated to the previous admission or diagnoses. For example, a readmission of a passenger in a car crash that was discharged three weeks prior with an acute Myocardial Infarction is currently captured in Medicare's readmission measures even though there is no relationship between the two events. Patients often obtain their treatment from the same facility in their community for different, unrelated reasons.

AHPA recommends that CMS collaborate with stakeholders to identify the best method for determining whether a readmission is related or not to the previous diagnosis. Identifying this relationship would ensure the fair adjustment of hospital payments and better align with Congress' intent, as specified under Section 3025 (q)5 II of the Affordable Care Act, which states that "such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital.")[5]

Changes to the Inpatient Only List

CMS often revises the Inpatient Only List (IPO) to account for services that the Agency determines can now be done safely in the outpatient setting. Currently, services listed in the IPO list can only be done in the inpatient setting. The removal of a service from the IPO list allows the service to be furnished in either the inpatient or outpatient settings depending on medical necessity.

To avoid confusion among clinicians, AHPA urges the Agency to review the criteria recommended by medical societies to determine inpatient or outpatient status before removing a procedure from the IPO list. For example, CMS could work with the Hip/Knee Society to establish the criteria for same-day joint replacements. Many claim denials are often experienced soon after a procedure is removed from the IPO list, as there seems to be a misalignment between the patient status criteria used by specialty organizations and the criteria used by Medicare contractors. Due to this issue, we recommend that CMS work closely with specialty organizations before removing a procedure from the IPO list to develop standard criteria that can be used by both physicians and Medicare contractors. For example, CMS could work alongside the American Academy of Orthopaedic Surgeons (AAOS) to create evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient

[5] Affordable Care Act. Section 3025 (q)5 II, page 292.

surgery. This would ensure adequate alignment between parties and reduce the administrative burden associated with claims being denied.

Prior-Authorization Process

Prior-authorization policies require getting approval before providing a service to the patient to ensure that the benefit will be paid. Prior authorization is used both by private insurance payers and Medicare, although it is less common within traditional Medicare.

Prior-authorization can be a powerful cost-saving tool; however, it can also be administratively burdensome. This is especially true for patient claims that have both Medicare and a private plan as payers. For example, a physician wishing to prescribe non-emergency transportation services to a dialysis patient may need to go through the prior-authorization process with both Medicare and the private insurance company. **To reduce this administrative burden, AHPA recommends that CMS work with payers to reduce the need for duplicative prior-authorization filings. CMS may also exempt providers from going through Medicare's prior-authorization process if the provider demonstrates that the claim is already going through prior-authorization with a private payer.**

Medicare as Secondary Payer

The Medicare as Secondary Payer (MSP) provisions help to ensure that primary payers pay claims before Medicare begins to pay the remaining balance. When a patient has both Medicare and another form of coverage, one will be noted as primary and the other secondary in the Common Working File (CWF). When Medicare is the secondary payer, primary payers must be billed first. If there is a long delay in payment by the primary payer, Medicare may make conditional payments.

Providers often experience administrative difficulties related to processing MSP claims, including late or back-loaded MSPs and incomplete primary payer information. Currently, there is no dedicated Medicare portal or department for providers' financial teams to contact for assistance in processing claims with Medicare as the secondary payer. **AHPA requests that CMS create a simple, online workflow for the MSP coordination of benefits process.** This workflow should provide clear visibility of the primary payer of a claim and an easy path to reconciliation.

Overlapping Claims Rejections

Overlapping claim rejections result when two claims share a date-of-service overlap. When an overlapping claim involves two different providers, the error must be resolved between the providers so

that CMS can process the claims in the correct sequence. Overlapping claims may occur between hospitals, Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs) or Home Health Agencies (HHAs).

Although Medicare providers are expected to work together to resolve errors, it is not always easy for one provider to know who the other overlapping party may be. Billing departments often spend large amounts of time calling general helplines within CMS as they gather information on the other overlapping party. **AHPA requests that CMS create an online process for communicating overlapping claims. AHPA also recommends that CMS create a specialty team to assist with overlapping claims' resolution and adjust claims as necessary.**

Medicare Notices

AHPA appreciates CMS' commitment to reducing administrative burden wherever possible. To make meaningful reductions, CMS should work collaboratively with State agencies to avoid conflicting requirements. **AHPA recommends that CMS convene a multidisciplinary team of experts—including revenue cycle, case management and physicians—to examine the roster of mandatory notices across the Medicare program and utilize the following principles**:

1. Mandatory notices should not be duplicative.
2. Notice requirements should be developed in collaboration with State governing agencies.
3. A notice's benefit to patients should outweigh its administrative cost.

Several mandatory notices unintentionally contribute to growing administrative burden, driving up the cost of delivering care without improving quality. Below are some examples of Medicare notices that significantly contribute to administrative burden.

Medicare Secondary Payer Questionnaire

Currently, CMS requires providers to deliver a questionnaire to all Medicare beneficiaries in order to determine whether Medicare is the primary or secondary payer. This questionnaire must be provided for each inpatient admission or outpatient encounter before submitting a claim to Medicare. According to CMS, the questions help the Agency update the beneficiary insurance information and verify that the beneficiary record is correct and up to date. This helps ensure that Medicare does not pay for items and services when other health insurance coverage is primary.

While we understand that CMS needs to collect beneficiary insurance information to protect the Medicare Trust Fund, we do not believe that health care providers are best suited to collect this information for CMS. The Medicare Secondary Questionnaire adds to the numerous documents that providers must deliver to patients at the bedside and that patients have to respond to while they are sick or eager to go home. We believe that this is a significant administrative burden for both providers and patients.

AHPA recommends that CMS require insurance companies to provide this secondary payer information to the Agency. Insurance companies already have access to beneficiaries' insurance information in their enrollment data. We believe that this is a more consumer-centric and efficient option. Moreover, CMS already requires insurance companies to submit Healthcare Effectiveness Data and Information Set (HEDIS) data to the Agency. Requiring insurers to submit enrollment data as well would be a reasonable option that would reduce provider burden. Providers would then be able to devote more time to patient care rather than providing documents to which insurers already have primary access.

Important Message from Medicare

Section 1866(a)(1)(M) of the Social Security Act requires hospitals to deliver an "Important Message from Medicare" (IM) to all hospital Medicare inpatients. The IM explains a beneficiary's rights as a hospital inpatient, including the right to appeal the provider's decision to be discharged from the hospital. On November 27, 2006, CMS revised the IM to require hospitals to issue the IM within two calendar days of the day of admission and obtain the signature of the beneficiary or his or her representative. The IM, or a copy of the IM, must also be provided to each beneficiary within two calendar days after discharge.

AHPA recommends that CMS modify the IM requirements so that hospitals are only required to provide the IM prior to the patient being discharged from the hospital. Due to the current requirement, hospitals often have to present the IM and obtain the beneficiary's signature twice, within two calendar days of admission and two calendar days after discharge. We do not think there is a need to provide a form twice to patients.

Hospice Notice of Election

Hospice providers are required to submit a Notice of Election (NOE) within five calendar days of the hospice admission. The NOE contains the start date of the beneficiary's election to receive hospice benefits and must be signed and dated correctly to be considered valid. Failure to submit a complete NOE

within the first five days of the hospice admission results in Medicare refusing payment for all claim lines.

AHPA believes the NOE to be duplicative, as hospice election data is already submitted with patient claims. It is very difficult for hospices to audit and submit this form separately during the first few days of the patient's stay. Patients often need the most attention during their first week of stay, as they work to get acclimated to their new environment. Completing, auditing and submitting the NOE during the first five days often lessens the amount of time hospice providers can spend with new patients. **We recommend that CMS use the hospice election data submitted with claims to verify that patients have chosen hospice care.**

Hospice Drug Management and Disposal Notification

Under Medicare's CoP, hospice facilities are required to provide each patient receiving a controlled substance with a copy of the facility's official policy on drug management and disposal. The facility must also provide education to the patient and their family on how to safely store, manage and discard their prescription.

AHPA agrees that patient education is a critical component in our fight against the opioid crisis. **Because many hospice agencies' official drug policies are highly technical and lengthy, we recommend that CMS instead require that patients be provided with accessible, plain-language versions of drug management and discharge policies.** AHPA believes that patient-friendly educational materials will be more impactful, empowering patients and families to safely manage their prescriptions.

Three-Day Skilled Nursing Facility Rule

In order for Medicare to reimburse for SNF services, CMS currently requires that patients have a three-day inpatient stay. Time spent in the hospital under observation or in an emergency room prior to admission does not count toward the beneficiary's three-day qualifying inpatient hospital stay. Waivers to this rule are available to participants of certain models developed by the Center for Medicare and Medicaid Innovation (CMMI), such as the Next Generation Affordable Care Organization (ACO) model and Track 2 of the Medicare Shared Savings Program (MSSP). The waivers are applied if a beneficiary meets all other CMS criteria for SNF admission, including:

- Being medically stable;
- Having confirmed diagnoses (e.g., does not have conditions that require further testing for proper diagnosis);

- Not requiring inpatient hospital evaluation or treatment;
- Having an identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis or through home health services.

AHPA recommends that the exemption to the three-day SNF rule be extended beyond CMMI models if a patient meets the criteria referenced above. If such criteria serves as a reasonable guardrail within certain CMMI models, we believe that the same should hold true for care provided outside of those models. CMS could also potentially require providers to conduct a functional assessment in the Emergency Department (ED) to determine whether a beneficiary meets SNF criteria. This would guarantee that patients are receiving health care services at the right setting of care without incurring unnecessary costs to the Medicare program. The three-day SNF rule, in addition to increasing administrative burden, is contributing to increased health care costs. For example, there are many instances in which a patient arrives to the ED and it is determined that the patient's medical condition will require treatment at an SNF. Due to the three-day rule, clinicians must unnecessarily admit the patient to the hospital just to meet the regulatory requirement. Not only does this increases Medicare costs, it places patients in the wrong setting of care. If the requirement's goal is to ensure the medical necessity of SNF services, we recommend that CMS uses the same criteria used in CMMI models for all SNF admissions.

Moreover, we strongly believe that setting-specific regulations should be reduced to allow for payments to be set based on patient characteristics rather than setting of care. Examples of these other setting-specific regulations include the 60 percent rule for Inpatient Rehabilitation Facilities (IRFs) and the 25-day Length of Stay requirement for LTCHs. As we move towards value-based care, these regulations impede timely access to care and adequate care coordination among providers.

Home Health Services

Outcome and Assessment Information Set

The Outcome and Assessment Information Set (OASIS) is a data collection tool developed to relay home health quality performance data to CMS. CMS requires that HHAs collect and transmit data for all qualifying patients being reimbursed by Medicare or Medicaid. OASIS-D, the most current version, includes both new items for collection and deduplicated standards. Our home health providers find the OASIS tool helpful in the assessment and care planning for home care patients but believe that it could benefit from additional refinements.

At times, the OASIS scoring is contradictory to clinical best practice and validated assessment methodology. For example, the surgical wound questions ask that clinicians assess the stages of wound or

pressure ulcers. The selection options differ from the standard stages outlined by the Wound, Ostomy and Continence Nursing Society guidelines. There are also prompts within the OASIS tool that use subjective language. For example, clinicians are often unclear on how the tool defines a patient's ability to perform a given action "safely." One clinician may believe that a patient walking 50 feet with a walker can perform the task safely; another may disagree, since they cannot walk unassisted. In both examples, significant clinician education has to be provided to train clinicians on how to use the tool and how to answer questions that may be vague or unintuitive. This education is time consuming for clinicians and expensive for the facility. **AHPA recommends that CMS work collaboratively with Congress and clinical experts to update the OASIS instrument.**

Face-to-Face Documentation

Currently, for home health care to be deemed medically necessary and reimbursed by Medicare, CMS requires a "face-to-face" evaluation by a clinician—physician, advanced practice nurse or physician assistant. Although a spectrum of clinicians may complete the evaluation, only a physician's signature may "certify" that the patient needs home care. Physicians cannot dictate their evaluation findings to the HHA staff. Without the required documentation, an HHA cannot bill for the care provided.

While we agree that home health care should be reserved for those patients with a true medical need, the stringent nature of the "face-to-face" documentation requirement is unduly burdensome. First, all patients who are being discharged by an acute facility into home care have already been seen by a physician. There is little value added by mandating "face-to-face" documentation for patients being discharged from the inpatient environment to home care. **At a minimum, AHPA requests that face-to-face documentation be include in the inpatient discharge process.**

Second, many HHAs have been subject to high denial rates for insufficient encounter documentation—some agencies experience up to 80 percent of claims denial.[6] Physicians require extensive training to know how to best complete the "face-to-face" documentation to meet CMS' expectations. Despite the training provided, mistakes in documentation result in a financial penalty for the HHA, not the physician completing the document. **Because HHAs are ultimately financially accountable for the documentation, AHPA recommends that they be allowed to complete the "face-to-face" documentation under physician advisement.** Under this policy, HHAs would draft the "face-to-face" documentation and physicians would only be required to sign it before a claim is submitted for payment.

[6] National Association for Home Care and Hospice, Implementation Procedures for the Physician Face-to-Face Encounter.

We believe this would reduce the documentation burden placed on physicians and the number of claims denied.

Physician Notification

Current home health guidelines require that a patient's physician be notified of all missed visits or changes to a patient's care plan. Plans of care and oral orders may be transmitted by facsimile or email to the physician for signature. Electronic signatures are now also permitted.

Our physicians have provided feedback that they would rather be notified of only significant care changes. For example, obtaining physician signatures after every delivery of an "as needed" Tylenol poses an unnecessary burden for that physician. **AHPA recommends that physicians be allowed to select the frequency and level of detail in their plan-of-care update notifications, as they do for the discharge summary reports, for each patient.**

Hospice Emergency Preparedness Testing

Beginning in November of 2017, hospice facilities were required to comply with emergency preparedness standards that were specified as a Medicare Condition of Participation (CoP). According to the new standards, every facility must have an emergency preparedness program, updated annually, which includes a training and testing program. Providers are required to conduct two testing exercises each year. One is to be a full-scale, community-based exercise that includes mock disaster victims, community emergency response teams and State health departments. The other can be a "table-top exercise" with clinically-relevant scenarios being narrated and simulated by hospice staff.

AHPA strongly supports the requirement for hospices to meet emergency preparedness standards as this helps to ensure patient safety. However, we recommend that CMS reduce the testing exercise requirement from twice a year to once per year, allowing the facility to select either a full-scale or "table-top exercise." This section of the emergency preparedness program requirements can be extremely burdensome for smaller hospice facilities with less resources. While large facilities—or those connected to robust health systems—can afford to perform multiple, full-scale training exercises each year, smaller hospice facilities often cannot.

The Protecting Access to Medicare Act of 2014

In 2014, Congress passed the Protecting Access to Medicare Act of 2014 (PAMA), which contains a variety of provisions impacting health care providers. Below are regulatory requirements related to PAMA that, if revised, could help reduce administrative burden.

Consulting Appropriate Use Criteria

PAMA requires that providers ordering advanced diagnostic imaging services consult Appropriate Use Criteria (AUC) prior to ordering a service. The consultation of AUC must be done via a CMS-qualified Clinical Decision Support Mechanism (CDSM), which would produce a unique number to be used in Medicare claims by providers furnishing the imaging services.

AHPA recommends that CMS exempt clinicians participating in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Quality Payment Program (QPP) from the AUC consulting requirements. Currently, providers participating in the Merit Based Incentive Payment System (MIPS) and the Alternative Payment Model (APM) tracks are already measured on the appropriate use of advanced imaging. An example of this is the requirement for providers to report the electronic Clinical Quality Measure "Use of Imaging Studies for Low Back Pain." Because QPP participating clinicians are already being held accountable for consulting AUC, we believe that CMS should exempt these clinicians from PAMA's AUC requirements. This would help reduce duplication and the corresponding administrative burden.

Clinical Laboratory Fee Schedule

PAMA requires clinical laboratories to report to CMS the payment rates paid by private payors for laboratory tests and the volume of tests paid at each rate. This data is used by CMS to inform how Medicare pays clinical laboratories for their services under the Medicare Clinical Laboratory Fee Schedule (CLFS).

The reporting of private payor rates is significantly burdensome to clinical laboratories. To allow these entities to dedicate more time to patient care, AHPA recommends that CMS require insurers to provide this payment information directly to the Agency. Insurers have primary access to their own payment rates and unlike clinical laboratories, are not directly engaged in patient care. Therefore, revising this regulatory requirement would relieve the documentation burden placed on clinical laboratories while meeting the goals of CMS' Patients Over Paperwork initiative.

Clinical Laboratory Improvement

All health system laboratories are regulated by the Clinical Laboratory Improvement Amendment (CLIA) program. The program establishes quality standards for all labs performing testing on humans, with the exception of research, and regularly tests labs for compliance. CLIA-certified labs are issued an identifying number under which all testing and education is conducted.

Because each lab is required to have a separate CLIA number, it makes it difficult for labs within the same health system to share resources and staff. For example, a laboratory technician scheduled at multiple labs would need to conduct trainings and competency tests for each separate lab at which he or she works. The technician cannot simply do the requisite quality training one time, because each lab—with its separate CLIA number—needs to document that every member of their staff has met the requirement. These duplicative trainings produce no added value for patients or the lab. **To reduce laboratory administrative burden, AHPA requests that CMS allow laboratories within the same hospital or health system to conduct trainings, testing and validation under a single CLIA number.**

The Implementation of Medicare Regulations

Currently, it is common for CMS to set January 1st as the effective day of any regulation due in the Calendar Year (CY) instead of the Fiscal Year (FY). Examples of this include the Outpatient Prospective Payment System (OPPS) and the Physician Fee Schedule (PFS) rules. Rules with a January 1st implementation date are generally issued in November. It is difficult for hospitals to properly prepare for implementation within this short, two-month window. This is particularly true for rules that contain policies requiring the development of educational materials and clinician training, changes to workflows and revisions to different technologies such as a hospital's Electronic Health Record (EHR). The timely and adequate compliance with Medicare regulations often entails significant costs that CMS should account for when setting a rule's implementation date. These include labor costs, investments in new technology and even costs in legal and auditing services.

Due to the issues referenced above, AHPA urges the Agency to refrain from using January 1st as the effective day for any regulation due in the CY. Instead, we recommend that CMS use the last day of January as the effective day. We believe this would help providers, hospitals and health systems to better prepare for the implementation of any new regulatory requirement.

Conclusion

AHPA commends the Agency for its work on the Patients Over Paperwork Initiative and we welcome the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact me at Carlyle.Walton@AdventistHealthPolicy.org or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

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